

REMARKS

1. In response to the Office Action mailed January 29, 2010, Applicants respectfully request reconsideration. Claims 1, 3, 5-7, 10-12, 14-17, 68 were last presented for examination. In the outstanding Office Action, claims 1, 3, 5-8, 10-12 and 14-17 have been rejected. By the foregoing Amendments, claims 1, 3, 6, 7, 17 and 68 have been amended, no claims have been cancelled, and claims 69-78 have been added. Thus, upon entry of this paper, claims 1, 3, 5-7, 10-12, 14-17 and 68-78 will be pending in this application. Of these twenty-three (23) claims, three (3) claims (claim 1, 72 and 76) are independent.

2. Based on the above Amendments and the following Remarks, Applicants respectfully request that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Interview of May 13, 2010

3. Examiner Trinh is thanked for extending the courtesy of an in-person interview to Applicant's representative, Martin Cosenza (Reg. No. 48,892), in which it was agreed that if amendments were made to the claims that further define the feedthrough or recite the action of removing the antenna from the template, such amendments would sufficiently differentiate the claims from GB 2166005 so as to remove it as a foundation for a prior art rejection. Also, it was agreed that further defining the phrase "hermetically sealed" on the record (Remarks) would sufficiently differentiate claims reciting a hermetic seal from GB 2166005 so as to remove it as a foundation for a prior art rejection. In reliance on this agreement, Applicants have amended the claims as seen above, and have added new claims.

Claim Rejections Under 35 U.S.C. §112, First Paragraph

4. In the Office Action, claims 6-7, 17 and 68 were rejected under 35 U.S. C. §112, first paragraph, as failing to comply with the enablement requirement. The Office Action states that the above claims contain subject matter which is not described in the specification in such a way as to enable one skilled in the art to make and/ use the invention. (*See*, Office Action, pg. 2.)

5. Specifically, the phrases "chassis and wall of a housing of an implantable component" as recited in claims 6-7, "encapsulating" recited claim 17, and "a housing of an implantable component" as recited in claim 68 are alleged as not being described in the specification and/or

drawings in such a way as to enable one skilled in the art to make and/or use the invention. (*See*, Office Action, pg. 2.) In response, Applicants traverse this rejection.

6. According to the Manual of Patent Examining Procedure (MPEP), “[a]ny analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention . . . Any part of the specification can support an enabling disclosure.” (*See*, MPEP § 2164.01; emphasis added.) For at least the following reasons, Applicants submit that the specification, when coupled with knowledge readily available in the art at the time Applicants’ filed their application, discloses sufficient information to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. Applicants further submit that now showing by the USPTO has been made that this is not the case.

7. As a preliminary matter, the Office Action contains only conclusory assertions that the claims rejected under 35 U.S. C. §112, first paragraph, are not enabled. No support or rationale for those assertions are provided. Moreover, the teachings of the art as a whole are nowhere addressed. Accordingly, the USPTO has not met its burden of establishing that the claims are not enabled.

8. Enabling support is not limited to the four corners of the specification and is not measured by the perceptions of an individual examiner. Rather, the standard is that of the ordinarily skilled artisan and the source of enabling information includes that which such an artisan presumably knows. That is, the correct test for enablement is whether the skilled person could make and use the claimed invention “from the disclosure in the [specification] coupled with information known in the art without undue experimentation.” (MPEP §2164.01, citing *United States v. Telectronics*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).)

9. Moreover, the burden is on the USPTO to show lack of enablement, and that burden is not satisfied by a mere assertion of such. In order to make a rejection, an examiner at the USPTO has the initial burden to establish a reasonable basis to question enablement. (MPEP §2164.04.) It has long been the rule that an examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled. (*In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).)

10. Applicants respectfully submit that the statements in the Office Action do not satisfy this burden. Applicants respectfully submit that the rejections in the Office Action are based on an incorrect standard for enablement. A person of ordinary skill in the art – given Applicants’ specification – would have been able to make and use the claimed inventions as of Applicants’ original filing date without undue experimentation. The USPTO has not met its burden in rejecting the claims as lacking enablement, and thus the rejections should be withdrawn for at least this reason.

11. Moreover, the claims are enabled. As to the specific claims rejected as lacking enablement, regarding practicing the methods of claims 6 and 7 with a feedthrough member comprising portions each configured to be mounted on one of either a chassis and wall of a housing of an implantable component, the present specification clearly provides sufficient information to satisfy the enablement requirement of Section 112. Specifically, the specification states that “[t]he feedthrough member is adapted to provide electrical connection through the chassis or wall of the housing whilst also ensuring hermetic sealing of the housing” and that “the feedthrough member 11 is mountable in a wall or chassis of a housing 14 and comprises a first portion 15 and a second portion 16.” Moreover, as described throughout the specification text and shown in the figures, the antenna is used as an element of an implantable component. (*See*, Applicants’ specification, page 3, lines 22-24 and page 15, lines 31-34, respectively, and FIG. 1a.) Furthermore, it is known to one of ordinary skill in the art that a feedthrough is a component which provides an electrical connection through another component.

12. The Merriam Webster dictionary defines a chassis as “the supporting frame of a structure,” and defines housing as “something that covers or protects.” Applicants assert there is sufficient information on the record to establish that one of ordinary skill in the art would have been enabled to practice the method as recited with a feedthrough member comprising portions each configured to be mounted on one of either a chassis and a wall of a housing of an implantable component. Based on the figures and the specification, the person of ordinary skill would be able to implement the invention without undue experimentation.

13. Regarding claim 17 and the action of encapsulating the feedthrough member and at least one wire, Applicants’ specification states that “the method can further include the step of encapsulating the housing, feedthrough and antenna in an electrically insulating material.” (*See*, Applicants’

application as filed, page 7, lines 31-36.) Further, Applicants' specification states that "the encapsulation step involves placing the components in a mould, which is then filled with a biocompatible material." (*See*, Applicants' application as filed, page 21, lines 8-12). Applicants' application then provides further examples of the material that may be used to fill the mould. In view of these explicit teachings of Applicants' specification, Applicants assert that the action of encapsulating the feedthrough member and at least one wire as recited in claim 17 is sufficiently enabled. The person of ordinary skill would be able to practice claim 17 without undue experimentation.

14. Regarding practicing the method of claim 68 with "a housing of an implantable component," Applicants' specification states that "the feedthrough member 11 . . . comprises a first portion 15 and a second portion 16. Both of the portions 15, 16 have a plurality of conductive posts extending through an electrically insulating block that hermetically seals the housing 14." (*See*, Applicants' application as filed, page 15, lines 31-34.) Applicants' specification further depicts a housing 14 in FIGs. 1a-1d.) In view of these explicit teachings of Applicants' specification, Applicants assert that the method steps recited in claim 68 are sufficiently enabled. The person of ordinary skill would be able to practice claim 68 without undue experimentation.

15. Therefore, in light of the sufficient information identified above in the present specification, Applicants assert that the claimed invention is enabled and rejections are thus improper. Accordingly, reconsideration and withdrawal of the rejections is requested. If the PTO disagrees with the above assertions, Applicants respectfully request that the PTO provide specific reasons explaining why the above phrases are not enabled rather than conclusory statements. Without such explanation, Applicants find it difficult to respond to the Examiner's rejections to the above claims.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

16. The Office Action as rejected claims 3, 6-7, 16-17 and 68 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully disagree, although, in order to advance prosecution, and without prejudice or disclaimer, Applicants have made amendments to some of these rejected claims.

17. Regarding claims 3, 16 and 17, Applicants respectfully submit that the amendments to

claim 3 render the rejection of claims 3, 16 and 17 moot.

18. Regarding claims 6-7, Applicants have amended claims 6 and 7 to recite that the feedthrough member comprises first and second *feedthrough member* portions. Accordingly, there can be no way to conflate the first and second portions of the wires with the first and second portions of the feedthrough members. Applicants submit that this amendment to claims 6 and 7 renders the rejection of claims 6-7 moot.

19. Regarding claim 68, Applicants submit that, as understood by one of ordinary skill in the art, a hermetic seal, for practical purposes, is considered an airtight seal, intended to secure against the entry of of liquids, microorganisms, and other foreign bodies. Websters dictionary defines hermetically as “so as to be airtight.” It is respectfully submitted that a “feedthrough member [] configured to provide a hermetically sealed electrical connection through a housing” is not indefinite. Withdrawal of the rejection is requested.

Drawings Objection

20. The Office Action contains an objection to the drawings under 37 C.F.R. § 1.83(a) for allegedly failing to show every feature of the invention specified in the claims. (*See*, Office Action, pg. 3.) In particular, the Office Action states that the “claimed subject matter *i.e.*, ‘first and second portions each configured to be mounted on either one of a chassis and wall of a housing if an implantable component,’ (claims 6-8) and ‘the feedthrough member is configured to provide a hermetically sealed electrical connection through a housing of an implantable component’ (claim 68), must be shown or the feature(s) canceled from the claim(s).” Applicants respectfully disagree.

21. Applicants assert that the features of claims 6-7 and 68 are shown in the drawings. For instance, the drawings include a housing 14 having a chassis and wall, a feedthrough member 11 comprising a first portion 15 and a second portion 16, and a wire 18, as shown in FIGs. 1a and 1b. Moreover, the drawings show, according to FIG. 1a, “both of the portions 15, 16 have a plurality of conductive posts extending through an electrically insulating block that hermetically seals the housing 14. In the depicted embodiment, the feedthrough member 11 is usable for both the wires feeding back from the electrodes [] of an intracochlear array and the wire or wires that will comprise the antenna coil.” (*See*, Applicants’ originally filed application, paragraph spanning pages 15-16 and FIG. 1a.) Inherently, the figures show first and second portions 15, 16 configured to be mounted on the housing 14, as shown.

22. Further, regarding the hermetically sealed electrical connection, this is a feature that does not avail itself to illustration in a drawing, just as is the case with the feature of an “electrical connection.” One may show a connection in a figure, but one cannot show that it is an electrical connection. That specificity is to be described in the specification. Along the same lines, Applicants illustrate a feedthrough member sealed as claimed, and specify in the specification that the seal is a hermetic seal. That is, it is sufficient to simply show the feedthrough members, and identify in the specification the characteristics of the feedthrough members. Therefore, Applicants submit that the objections to the drawings are improper, and should be withdrawn.

Claim Rejections Under 35 U.S.C. §102

23. The Office Action rejects claims 1, 5 and 10-12 under 35 U.S.C. §102(b) as being anticipated by GB 2166005 to Miura (hereinafter “Miura”). In response, in order to advance prosecution, and without prejudice or disclaimer, Applicants have amended claim 1 as shown above, in accordance with the interview of May 13, 2010, and respectfully submit that the claims are allowable for at least the reasons agreed upon in the interview.

24. Specifically, claim 1 now explicitly defines the feedthrough member as a member that is “configured to provide an electrical connection through a wall of an implantable component implantable in the recipient along with the antenna.” This language is supported in Applicants’ originally filed specification at page 8, lines 12-14. As was agreed upon during the interview, this patentably distinguishes the claim from Miura.

Claim Rejections Under 35 U.S.C. §103

25. The Office Action rejects claims 14-15 under 35 U.S.C. 103(a) as being unpatentable over Miura. Applicants respectfully assert that, for at least the reasons discussed above with reference to claim 1, the rejections under 35 U.S.C. §103 are now moot, as claim 1 is patentable in view of Miura.

Dependent Claims

26. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicants respectfully assert that the dependent claims are also allowable over the art of record.

New Claims

27. Applicants have added new independent claims 72 and 76. These new claims recite features agreed upon in the May 13, 2010 interview as patentably distinguishing from Miura. Specifically, claim 72 recites a method of forming an antenna, comprising obtaining a feedthrough member configured to provide a hermetically sealed electrical connection through a housing of an implantable component implantable in the recipient along with the antenna, and connecting the antenna to that feedthrough member. Dependent claim 74, which depends from claim 72, further

recites the action of mounting the feedthrough member on a wall of the housing and providing by that action a hermetically sealed electrical connection through the wall of the housing of the implantable component. As was agreed during the May 13, 2010 interview, such method actions patentably differentiate from Miura, and thus these claims are allowable at least in view of Miura.

28. Claim 76 recites a method of forming an antenna, comprising winding the at least one wire at least once around the antenna template and removing the at least one wire from the antenna template after winding the at least one wire at least once around the antenna template. As was agreed during the May 13, 2010 interview, such method actions patentably differentiate from Miura, and thus these claims are allowable at least in view of Miura.

Conclusion

29. In view of the foregoing, Applicants respectfully submit that this application is now in condition for allowance. A notice to this effect is respectfully requested.

30. Applicants make no admissions by not addressing any outstanding rejections or basis of rejections. Furthermore, Applicants reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Thus, cancellations and amendments of above claims should not to be construed as an admission regarding the patentability of any claims.

Dated: June 1, 2010

Respectfully submitted,

Electronic signature: /Michael G. Verga/
Michael G. Verga

Registration No.: 39,410
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 331-7111
(202) 293-6229 (Fax)
Attorney for Applicants